K122306

**510(K) SUMMARY**

MAR 8 2013

**Applicant:**
Synovis Surgical Innovations
2575 University Avenue West
St. Paul, MN 55114-1024
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Fax: 651-642-9018

**Contact Person:**
Jodi Jorgenson
Regulatory Affairs Manager
At address above

**Date Prepared:**
July 31, 2012

**Device Trade Name:**
Synovis Collagen Matrix (TBD)

**Common Name:**
Pericardial Patch

**Classification Name:**
21 CFR 870.3470: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate or polytetrafluoroethylene
Product Code: DXZ

**Predicate Devices:**

- Synovis Surgical Innovations, Veritas® Collagen Matrix:
  K002233, K030879, K062915
- Synovis Surgical Innovations, Supple Peri-Guard® Pericardium with APEX Processing:
  K921895, K923657, K961810, K983162
- Synovis Surgical Innovations, Peri-Guard® Pericardium with APEX Processing:
  K821532, K833021, K842066, K961811, K971726, K983162
- CorMatrix Cardiovascular Inc, CorMatrix® ECM™ for Pericardial Closure:
  K051405

**Device Description:**
Synovis Collagen Matrix is an implantable biologic patch comprised of non-crosslinked bovine pericardium.

**Statement of Intended Use:**
Synovis Collagen Matrix is intended for the reconstruction and repair of the pericardium.

**Substantial Equivalence:**
The indications for use for Synovis Collagen Matrix for reconstruction and repair of the pericardium are substantially equivalent to the indications for use of the predicate devices. Any differences in the technological characteristics between the devices do not raise any new issues of safety or efficacy. Therefore, Synovis Collagen Matrix for reconstruction and repair of the pericardium is substantially equivalent to the predicate devices.

**Summary/Comparison of Technological Characteristics:**
The safety and performance of Synovis Collagen Matrix was evaluated through non-clinical testing.

The non-clinical testing assessed the following aspects of the device:

- Suture retention
- Thickness
- Amine index
- Tensile
- Burst
- Sterilization validation
- Packaging and shelf-life
- Biocompatibility
- Animal studies

Bench testing results support the performance requirements for Synovis Collagen Matrix. Biocompatibility testing was performed in accordance to ISO 10993-1 (*Biological Evaluation of medical devices – Part 1: Evaluation and testing within a risk management process).*

Various animal studies were conducted to support the safety and efficacy of Synovis Collagen Matrix. Systemic toxicology was evaluated in a swine model, and the results indicated that at all time points, there was no detectable systemic or site-specific toxicity. Histological examination revealed the device was readily remodeled and integrated into the adjacent host connective tissue.

Synovis Collagen Matrix was also used to repair the tissue "stump" remaining after pneumonectomy and defects in the chest wall in a canine model. Results indicated no systemic or implant site specific toxicity, elicits minimal inflammation, minimal foreign body response or fibrosis, complete healing of the bronchial stump with no air leaks and repaired chest wall defects with sufficient mechanical integrity that remained hernia free throughout the 90 day post-implant period. Histological analysis demonstrated that Synovis Collagen Matrix undergoes extensive remodeling through host tissue integration of the implant and leads to formation of connective tissue that is indistinguishable from adjacent host tissue.

Adhesion formation was evaluated in a rat model, and the results confirmed that Synovis Collagen Matrix demonstrates minimal tissue attachment to the device in case of direct contact with viscera. These animal studies indicate that the device is safe and confirms product functionality.

**Conclusions:**
Synovis Collagen Matrix for reconstruction and repair of the pericardium is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 8, 2013

Synovis Surgical Innovations
C/O Jodi Jorgenson, Regulatory Affairs Manager
2575 University Avenue West
St. Paul, MN 55114-1024

Re: K122306
Trade/Device Name: Synovis Collagen Matrix
Regulation Number: 21 CFR 870.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: DXZ
Dated: February 20, 2013
Received: February 22, 2013

Dear Ms. Jorgenson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K122306

Device Name: Synovis Collagen Matrix

Indications For Use:

Synovis Collagen Matrix is intended for the reconstruction and repair of the pericardium.

Prescription Use __X_____ AND/OR Over-The-Counter Use _____

(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Owen P. Faris -S
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